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K003425

SECTION II. SUMMARY OF SAFETY AND EFFECTIVENESS

A. DEVICE NAME

Proprietary Device Name:	CLIRANS E-Series Hollow Fiber Dialyzers
Classification Name:	High Permeability Hemodialyzer
Common Name:	Hollow Fiber Dialyzer

B. PREDICATE DEVICE

The predicate devices are the Althin Altra-Flux 140 (K945620) and the Althin AF180 (K992564).

C. INTENDED USE

The CLIRANS E-Series Hollow Fiber Dialyzers are indicated for use whenever a patient is found to be in acute or chronic renal failure and hemodialysis is prescribed by a physician. The device should be used only at the direction of a physician who has evaluated all of the pertinent features of the patient's illness. This device is indicated for single use only.

This is the same intended use as the predicate device.

D. DESCRIPTION

The CLIRANS E-Series Hollow Fiber Dialyzers are comprised of E and EE type dialyzers. These dialyzers have a bioactive membrane comprised of vitamin E coated onto block copolymer, which are bonded to the cellulose membrane. The dialyzers are high flux devices and are labeled for single use only.

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E. PRINCIPLE OF OPERATION / TECHNOLOGY

The CLIRANS E-Series Hollow Fiber Dialyzers operate in the following manner. Blood is pumped via a roller pump from the artery of the patient into the arterial end of the dialyzer. The blood travels down through the dialyzer fibers where waste products pass through the membrane of the dialyzer into dialysate, which is constantly circulating through the dialyzer on the outside of the hollow fibers. Blood then exits the venous end of the dialyzer back to the patient.

The predicate device operates in the same manner.

F. DESIGN / MATERIALS

The CLIRANS E Dialyzers use similar materials as the predicate device. Differences in materials between the CLIRANS E-Series Dialyzers and the cleared Althin dialyzers raise no new issues of safety and effectiveness.

G. SPECIFICATIONS

Specifications of the Hollow Fiber

	Inside Diameter (μ)	Wall thickness (μ)	Effective surface area (m^2)
CL*E12NL	200	23	1.2
CL*E15NL	200	23	1.5
CL*E18NL	200	23	1.8
CL*EE12NL	200	26	1.2
CL*EE15NL	200	26	1.5
CL*EE18NL	200	26	1.8
Altra-Flux 140	195	30	1.4
AF180	195	30	1.8

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H. PERFORMANCE

The performance of the CLIRANS E-Series Hollow Fiber Dialyzers is substantially equivalent to the performance of the cleared Althin Altra-Flux and AF series dialyzers. The following tests were performed to demonstrate the substantial equivalence of the devices.

- In vitro clearance (Urea, Creatinine, Phosphate and Vitamin B12)
- Ultrafiltration coefficient (KuF) using bovine blood
- Flow resistance (Pressure drop)
- Priming volume
- Structural integrity
- Sieving Coefficient

I. ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated in accordance with EN554 and ISO 11134 to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Blood contacting materials were tested in accordance with the test recommendations in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." The dialyzer is categorized as an "External Communicating Device, Circulating Blood, Prolonged contact duration (24 hrs – 30 days). The blood contacting materials were found to be biocompatible.

Expiration dating for the CLIRANS E-Series Dialyzers will be 18 months.

J. SUBSTANTIAL EQUIVALENCE

The CLIRANS E-Series Hollow Fiber Dialyzers submitted in this 510(k) are substantially equivalent in intended use, design, principles of operation / technology, materials, specifications and performance to the cleared Althin ALTRA-FLUX and AF Series dialyzers. Differences between the devices do not raise any issues of safety or effectiveness.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

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K. SUBMITTER INFORMATION

Name and Address: Terumo Medical Corporation
125 Blue Ball Rd.
Elkton, MD 21921

Contact Person: Yuk-Ting Lewis
Senior Regulatory Specialist
Phone: 410-392-7213
Fax: 410-398-6079
Email: yukting.lewis@terumomedical.com

Date Prepared: Oct. 31, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2001

Ms. Yuk-Ting Lewis
Senior Regulatory Specialist
Terumo® Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
ELKTON MD 21921

Re: K003425
CLIRANS® E-Series Hollow Fiber Dialyzers
Dated: November 2, 2000
Received: November 3, 2000
Regulatory Class: II
21 CFR §876.5860/Procode: 78 KDI

Dear Ms. Lewis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): _____

Device Name: CLIRANS® E-Series Hollow Fiber Dialyzers

Indications For Use:

The CLIRANS® E-series Hollow Fiber Dialyzers are indicated for use whenever a patient is found to be in acute or chronic renal failure and hemodialysis is prescribed by a physician. The device should be used only at the direction of a physician who has evaluated all of the pertinent features of the patient's illness. This device is indicated for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003425